Podiumsdiskussion: Herausforderungen und Chancen der Zusammenarbeit

Ändert die Implementierung der EU HTA Verordnung das AMNOG Verfahren?

Informationsveranstaltung des Gemeinsamen Bundesausschusses

10. November 2023

Dr. Vanessa Elisabeth Schaub / F. Hoffmann-La Roche, Ltd.

EU HTA Roche Team
For faster access in Europe

Disclaimer

Employee of F. Hoffmann-La Roche Ltd.

The views expressed are those of the author and do not necessarily reflect the views of the employer. Any mistakes are the responsibility of the author.

Agenda

Roche's Vision for EU HTA

Roche's Approach to internal and external EU HTA readiness

Observations regarding the direction of travel of the EU HTA R implementation

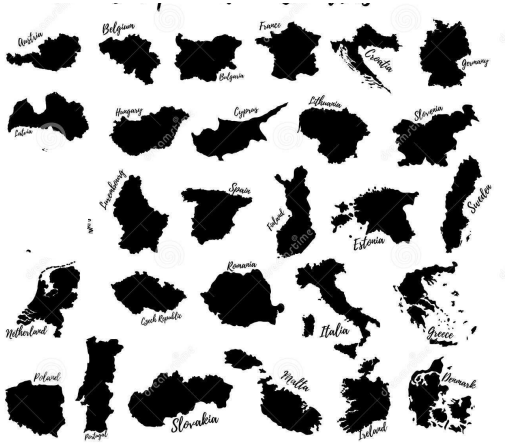
AMNOG in context of EU HTA

Roche's Vision for EU HTA

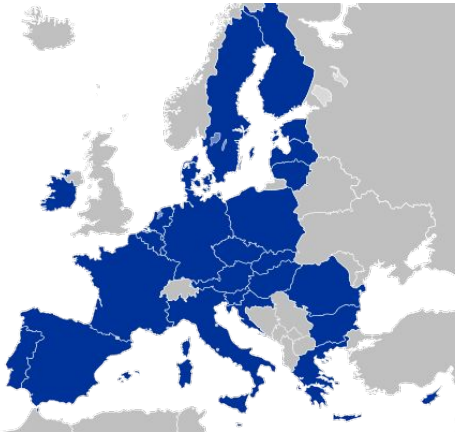
Roche's Vision for EU HTA

EU-wide singular HTA approach enabling accelerated patient access

EU HTA system delivers timely and high-quality assessments and becomes a driver of accelerated patient access and improved value recognition for our Roche solutions across the EU



- Enhance innovation
- Simplify processes - avoid duplication
- Reduce inequity across Europe
- Accelerate patient access



Roche’s approach to internal and external readiness

External milestones determine internal priorities

Internal Project Phases & Priorities after EUnetHTA Joint Actions

Simplified

Internal Planning	2022: Shape	2023: Build	2024: Test	2025: Succeed
	Leverage opportunities to go for JSC for molecules which are up for JCA as of 2025			
	Shape emerging EU HTA environment for JSC and JCA with focus on EUnetHTA 21 public consultations	Build internal organisational readiness: operating model, resourcing, capability building, training	Pressure test operating model & start prepare for JCA molecules in scope	Succeed with first mandatory JCAs

HTA = Health Technology Assessment; JCA = Joint Clinical Assessment; JSC = Joint Scientific Consultation

Cross-Functional and Multi-Dimensional Approach

Key Partnerships with Regulatory & EU Affiliates

Define the priorities, content, methods, and plan for effective communication and engagement with external stakeholders (e.g. public consultations EUnetHTA 21 / EC, HTA Coordination Group, multi stakeholder platforms)

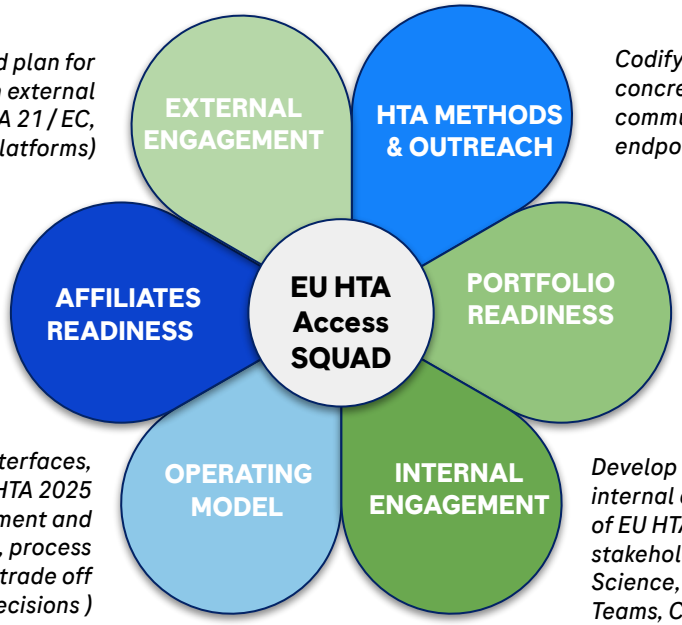
Codify existing content on HTA methods to ensure concrete, aligned positions and messages for communication / advocacy efforts (e.g. ITCs, endpoints including PROs)

Support affiliate internal readiness and accountability to meet EU HTA 2025 requirements and shape at the local level (e.g. local system mapping & gap analysis, risk identification, PICO pilots)

Ensure that strategies for Roche's current portfolio and future pipeline assets are informed by EU HTA 2025 requirements (e.g. strategic deep dives with selected brand teams, PICO pilots)

Identify the broad organizational structures, interfaces, processes and capabilities needed to imbed EU HTA 2025 considerations into early, strategic asset development and evidence planning (e.g. key partnerships, process bottlenecks, clear accountabilities including trade off decisions)

Develop content and methods to effectively (a) educate internal colleagues and stakeholders on the business impact of EU HTA2025 and (b) motivate action (e.g. key internal stakeholders such as Access, Regulatory, Data & Clinical Science, Safety, Medical Affairs, Development & Commercial Teams, Communications & Legal)



Observations regarding the direction of travel of the EU HTA R implementation

What is needed for a successful EU HTA framework

External Critical Success Factors & Policy Asks

Process & Governance	**HTDs must be recognised as key contributors** and stakeholders and are systematically and meaningfully included throughout the JCA process.
	The EU **JCA must be efficient and also workable for both HTDs and assessors** within the very limited procedural timelines.
	There must be **sufficient capacity and expertise at EU level** available for JSCs and for timely and high-quality JCAs.
	JCAs reports must provide interpretation and discussion of the clinical evidence, including the key findings and interpretation.
Methods	The EU JCA must accept a range of **different types of evidence,** which reflects the specifics of different clinical settings and clinical contexts. The principles for the acceptability of evidence should be consistently applied and predictable.
	The EU JCA must accept **surrogate, intermediate and novel clinical endpoints**, reflecting the reality, contexts and constraints of drug development.

What is needed for a successful EU HTA framework

External Critical Success Factors & Policy Asks

Process & Governance	**HTDs must be recognised as key contributors** and stakeholders and are systematically and meaningfully included throughout the JCA process.
	The EU **JCA must be efficient and also workable for both HTDs and assessors** within the very limited procedural timelines.
	There must be **sufficient capacity and expertise at EU level** available for JSCs and for timely and high-quality JCAs.
	JCAs reports must provide interpretation and discussion of the clinical evidence, including the key findings and interpretation.
Methods	The EU JCA must accept a range of **different types of evidence,** which reflects the specifics of different clinical settings and clinical contexts. The principles for the acceptability of evidence should be consistently applied and predictable.
	The EU JCA must accept **surrogate, intermediate and novel clinical endpoints**, reflecting the reality, contexts and constraints of drug development.

HTDs involvement to support high quality assessments

Key Findings

In **24 EU MS** (and Norway), there is the possibility for HTD-HTA(-like) assessors **interaction during the assessment phase** mainly to address questions from the assessors.

In **19 out the 24 EU MS** (and Norway), **HTDs** are also either required or offered the opportunity **to interact** with the HTA(-like) assessors **during the scoping phase**, and mostly in the format of a **pre-submission meeting**.

Pre-submission or consultation meetings aim to ensure the HTD provides the best quality HTA submission possible, in order to avoid challenges later on during the assessment

Policy Ask

- enough **capacity and resources to conduct regular and early JSCs** to inform the registrational studies
- **formal input from HTDs in particular into the PICO process** during the scoping phase by e.g. a re-established **scoping meetings**
- **exchange opportunities upon mutual request** from HTA assessor/co-assessor and / or HTD **during the assessment phase**

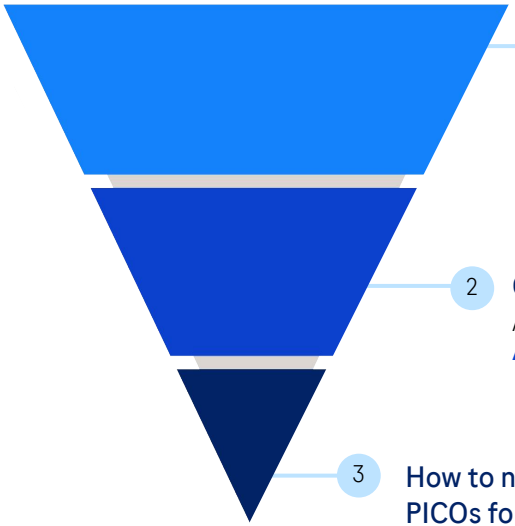
	HTD involvement	Interaction HTD-HTA/ HTA-like assessors	1	2	3	4
Austria	✓ (formal)	✓ (direct)	M	M/O	M/O	
Belgium	✓ (formal)	✓ (direct)	M/O	O	O	
Bulgaria	✓ (formal)	✓ (direct)	M	M/O	O	
Croatia	✓ (informal)	✓ (indirect/via PM)		M/O		
Czech Republic	✓ (formal)	✓ (indirect/via PM)	M/O	O		O
Denmark	✓ (formal)	✓ (direct)	M	O	O	O
Estonia	✓ (informal)	✓ (direct)		M/O		O
Finland	✓ (formal)	✓ (direct)	M	O	O	
France	✓ (formal)	✓ (direct)	M	O	O	M
Germany	✓ (formal)	✓ (indirect/via PM)	M	O	M	O&M
Greece	✓ (formal)	✓ (indirect/via PM)	O	O		O
Hungary	✓ (formal)	✓ (indirect/via PM)	M/O	O		
Ireland	✓ (formal)	✓ (indirect/via PM)	M	M	M	
Italy	✓ (formal)	✓ (indirect/via PM)	M	O		
Latvia	✓ (informal)	✓ (direct)	O	O		
Lithuania	✓ (formal)	✓ (direct)	M/O	O		
Netherlands	✓ (formal)	✓ (indirect/via PM)	M/O	M/O	M/O	
Norway	✓ (formal)	✓ (direct)	M/O	M/O	O	
Poland	✓ (formal)	✓ (direct)		M/O		O
Portugal	✓ (informal)	✓ (indirect/via PM)		M/O	O	
Romania	✓ (formal)	✓ (indirect/via PM)	O	M/O	O	
Slovakia	✓ (formal)	✓ (indirect/via PM)	M	M		
Slovenia	✓ (informal)	✓ (indirect/via PM)	M/O	M/O	M/O	
Spain	✓ (formal)	✓ (direct)		M/O		M
Sweden	✓ (formal)	✓ (direct)	O	O	M/O	

Notes: "Formal" means that there is a written procedure describing how HTD is involved).
O=Offline (e.g. via email/letter exchange) **M**= Meeting (virtual or in person); **PM**=project manager (or equivalent)
1 Prior to Dossier Submission **2** During Assessment **3** Prior to HTA report finalization **4** After HTA report finalization

Interaction HTD-HTA(-like) assessors
No interaction HTD-HTA(-like) assessors

Primary source: Roche survey to EU Affiliates - no data available for Luxembourg, Malta and Cyprus

EU level PICO consolidation based on transparent & objective criteria to ensure workability for all sides



1 **Started off the exercise with 51 PICOs…**
… as a result of a PICO survey to the 27 Roche Affiliates across the EU. High number of PICOs is mainly driven by the significant number of comparators of interest in breast cancer.

2 **Consolidated to 26 PICOs**
Applying the EUnetHTA21 guidance including the **AND/OR rule** and assumptions.

3 **How to narrow down the number of PICOs for a workable dossier submission and assessment?**
Roche will make the **best assumptions** and choices to make the **dossier workable.**

Policy Ask

- **transparent & objective consolidation criteria to allow predictability** and frontload the work at risk within meaningful limits
- **HTD involvement in the scoping process** on a mandatory basis for the PICO definition (see earlier point)
- **restriction to the most meaningful PICOs to ensure workability** on all sides within very restrictive timelines
- HTDs have **access to the input** of member states for the **PICO survey**
- adherence to the **submission dossier timelines** set out in the Regulation (**45 days prior to CHMP** opinion).

What did Roche do to get there?

1. Built an internal PICO survey pre-filled with available information from Medical guidelines etc. 2. Educated its 25 Affiliates to the PICO concept 3. 25 Roche Affiliates were engaged and replied within 3 weeks during the summer 4. Consolidated the results on the basis of the EUnetHTA21 D4.2 Scoping guidance

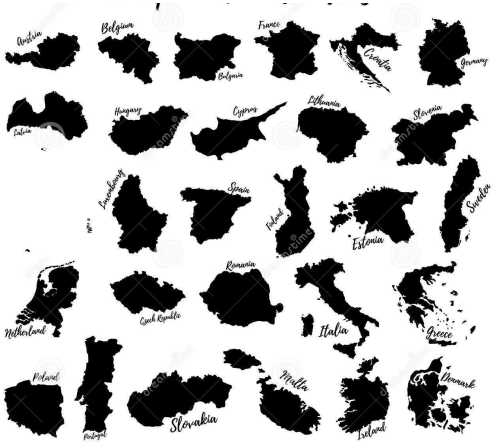
AMNOG in context of EU HTA

Questions & Considerations for AMNOG

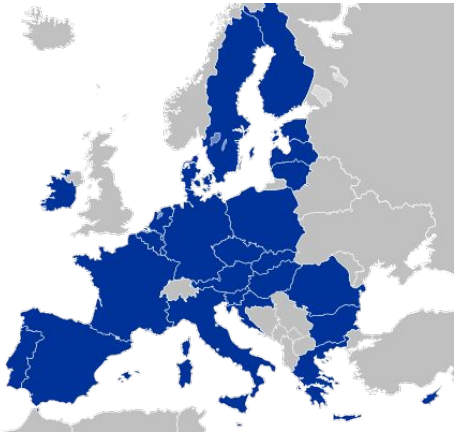
- ➔ Preserve the earliest possible start of the AMNOG procedure after EMA approval to prevent delays for patient access and reimbursement
  - ◆ Build in JCA report during assessment phase
  - ◆ Resolution needed for late stage label changes
- ➔ Preserve highly valuable engagement along the drug development cycle between HTAs and HTDs
  - ◆ Elevate German best practice example to the EU level
- ➔ Ensure usability of JCA report for all European countries and for Germany
  - ◆ As much European level consolidation and harmonisation as possible
  - ◆ Decrease scope of national Delta dossier
- ➔ Clarify in scope / out of scope JCA / AMNOG molecules, e.g.
  - ◆ Combination of NME (in JCA scope) and already launched product
  - ◆ Launched product - new mode of application

EU HTA - An opportunity “too big to fail”

Collaboration across all stakeholders is key to make it a success



- Enhance innovation
- Simplify processes - avoid duplication
- Reduce inequity across Europe
- Accelerate patient access



Doing now what patients need next